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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,908

05/30/2006

Akio Imai

0152-0734PUS1

9354

2292 7590 03/24/2009  
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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

03/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,908	<b>Applicant(s)</b> IMAI ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/30/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/30/06, 8/30/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. This application is a 371 of PCT/JP05/08028.

Claims 1-15 are pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

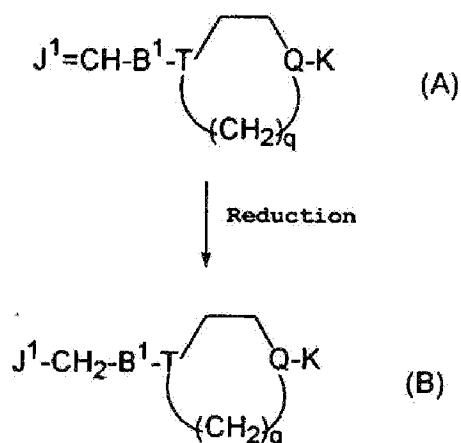
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP-A-1-79151 or JP 61-JP 4-187674 (1449) in view of JP 64-79151 (1449) supplemented with US 4,895,841 and JP A-4-187674 supplemented with CA 118.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

The two Japanese references were submitted by applicants without English translation. Therefore, the description of the references were relied upon as recited on page 3-5 of the specification:

Patent Document 1 [ JP –A-1-79151 recited on 1449] discloses a reaction formula as shown below (page 15, lower right column, line 2 to page 16, upper left column, line 1 of the specification).

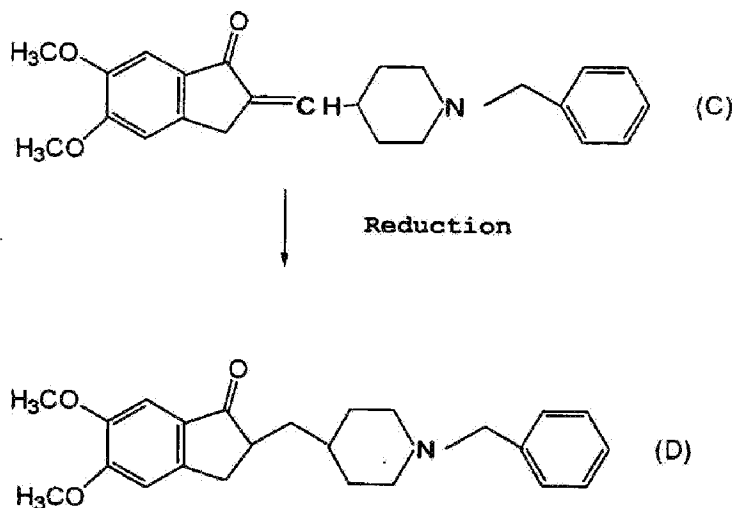


That is, Patent Document 1 [JP A-1-79151]discloses a process for preparing a compound of the formula (B) by reducing a compound of the formula (A) that contains a compound in which J<sup>1</sup> is indanone, and describes that "when carrying out catalytic reduction, use of, for example, palladium carbon, Raney nickel, rhodium carbon, or the like as a catalyst leads to a favorable result" (page 16, upper left column, lines II to 13 of the specification). Moreover, as a process for preparing donepezil hydrochloride using donepezil as a raw material, a concentrated residue of the compound of the structural formula (II) is dissolved in methylene chloride, and the mixture is treated with 10%hydrochloric acid-ethyl acetate is exemplified (Example 4).

However, Patent Document 1 [JP A-1-79151] shows examples of a catalyst to be used in catalytic reduction such as palladium carbon, Raney nickel, rhodium carbon, but does not mention any specific catalytic reduction process. Patent Document 1 only discloses a production example (Example I) that uses 5% rhodium-carbon as a catalyst, and a production example (Example 4) that uses 10% palladium-carbon as a catalyst. There is no disclosure about a catalytic reduction process using Raney nickel as a catalyst.

Patent Document 2 [JP patent 2578475 recited on 1449 as 2-169568] discloses a reaction formula as shown below (page 3, lines 6-8 of the specification, see patent family US 4895841 col. 14-16).

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That is, Patent Document 2 [JP 257475] discloses a process for preparing a compound of the formula (D) that is a desired substance obtained by catalytically reducing a compound of the formula (C), and describes that "when carrying out catalytic reduction, use of, for example, palladium carbon, Raney nickel, rhodium carbon, or the like as a catalyst leads to a favorable result" (page 3, lower right column, line 6 to line 4 from the bottom of the specification). (see US 4,895,841 col. 14 patent family).

Document 3 [JP A-4-187674] disclosed using rhenium as catalyst in preparing the claimed formula II compound from the claimed formula III.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the prior art is instead of the exemplified species of catalysts, the instant claims employed the specific non-exemplified Raney nickel. The dependent claims limited the process with more explicit operational parameters such as temperature, pressure, solvents etc.

*Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)*

One having ordinary skill in the art in possession of the above references would be motivated to employ any generically taught hydrogenation catalyst for the particular process because the prior art has explicitly demonstrated the variation of operable catalysts and generically provided optional variations for the exemplified species.

Applicants' attempt to obviate the prima facie obviousness by comparing product purity with the products made by prior art process does not offer any unexpected result as to support any obviation of the obviousness. Please note that there is no statistics as to the comparison whether the purity is "statistically significant" over the purity of the prior art. Further, it was noted that the prior art process, after production of the desired formula II, the product was dried and the residue was obtained. In the instant process, after production of the formula II (see examples 1-5, 7-9) "subsequently" the product was crystallized from ethanol. Further crystallization is conventional skill in purification of a product (see Cheronis). Therefore, the purity between the instant process and the prior art process is apparently due to further

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purification step before harvesting or further derivatization. The higher purity is an expected result well known in the chemical art.

The more explicit and specific reacting conditions in the dependent claims are well known in the chemical art being effect oriented manipulation for better yield. In re Woodruff 16 USPQ2d 1934; In re Boesch 105 USPQ 215. Such modification has been set forth by the court to be prima facie obvious over the known process in absent of unexpected results.

Changing parameters such as choosing an alternative species of catalyst generically disclosed of the prior art, is expected to have some variation. Applicants' attempt to obviate the established prima facie case of obviousness failed to support unexpected result.

**3.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Mar. 18, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*